

(19) World Intellectual Property
Organization
International Bureau



(43) International Publication Date
4 August 2005 (04.08.2005)

PCT

(10) International Publication Number
WO 2005/070897 A1

(51) International Patent Classification⁷: C07D 233/60,
A61K 31/4174, A61P 31/10

(21) International Application Number:
PCT/HU2005/000002

(22) International Filing Date: 25 January 2005 (25.01.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
P0400270 27 January 2004 (27.01.2004) HU

(71) Applicant (for all designated States except US):
RICHTER GEDEON VEGYÉSZETI GYÁR RT.
[HU/HU]; Gyömrői út 19-21., H-1103 Budapest (HU).

(72) Inventors; and

(75) Inventors/Applicants (for US only): CZIBULA, László [HU/HU]; Gergely u. 48., H-1103 Budapest (HU). DOBAY, László [HU/HU]; Kertész u. 42-44., H-1073 Budapest (HU). WERKNÉ PAPP, Éva [HU/HU]; Noszlopy u. 41/D, H-1103 Budapest (HU). NAGYNÉ BAGDY, Judit [HU/HU]; Pajkos u. 23/A, H-1119 Budapest (HU). SEBŐK, Ferenc [HU/HU]; Fáy u. 67., H-5800 Mezőkovácsháza (HU).

(74) Common Representative: RICHTER GEDEON VEGYÉSZETI GYÁR RT.; Gyömrői út 19-21., H-1103 Budapest (HU).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI,

GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Declaration under Rule 4.17:

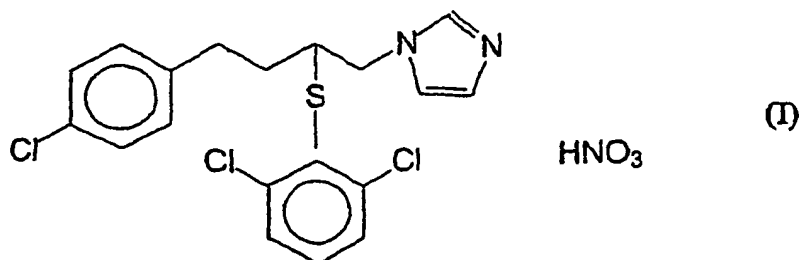
— as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IS, IT, LT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG)

Published:

— with international search report

[Continued on next page]

(54) Title: HIGH PURITY BUTOCONAZOLE NITRATE WITH SPECIFIED PARTICLE SIZE AND A PROCESS FOR PREPARATION THEREOF



(57) Abstract: One object of the invention is high purity butoconazole nitrate of the formula (I) (I) containing maximum 0.1 wt % of chemical impurities, wherein at least 95% of the particles of the substance are below 75µm by diameter, whereas at least 99% of the particles are below 250µm by diameter, and process for its preparation. A pharmaceutical composition comprising as active ingredient, high purity butoconazole nitrate of specified particle size in admixture with known auxiliaries is also within the scope of

WO 2005/070897 A1



For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.